KAMADA LTD
Form 20-F
March 26, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report: Not applicable

For the transition period from ____ to _____

Commission file number 001-35548

Kamada Ltd.
(Exact name of registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

7 Sapir St.
Kiryat Weizmann Science Park
P.O Box 4081

Ness Ziona 74140
Israel
(Address of principal executive offices)

David Tsur, Chief Executive Officer
7 Sapir St., Kiryat Weizmann Science Park
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+972 8 9406472
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of Each Class	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	The NASDAQ Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act. None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

As of December 31, 2013, the Registrant had 35,959,939 Ordinary Shares outstanding (excluding treasury shares).

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

o Yes x No

If this report is an annual report or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

o Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

x Yes o No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer o Accelerated filer o Non-accelerated filer x

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP o	International Financing Reporting Standards as issued by the International Accounting Standards Board x	Other o

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 o

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

o Yes x No

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In this Annual Report on Form 20-F ("Annual Report"), unless the context indicates otherwise, references to "NIS" are to the legal currency of Israel, "U.S. dollars," "$" or "dollars" are to United States dollars, and the terms "we," "us," "our compan "our," and "Kamada" refer to Kamada Ltd., along with its consolidated subsidiaries.

This Annual Report contains forward-looking statements that relate to future events or our future financial performance, which express the current beliefs and expectations of our management. Such statements involve a number of known and unknown risks, uncertainties and other factors that could cause our actual future results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases. We have based these forward-looking statements largely on our management's current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- our belief that our relationships with our strategic partners will continue without disruption;
- our ability to procure adequate quantities of plasma and fraction IV which are acceptable for use in our manufacturing processes from our suppliers;
- our ability to maintain compliance with government regulations and licenses;
- our ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;
- our belief that the market opportunity for Alpha-1 Antitrypsin ("AAT") products will grow;
- our belief that the potential world market for AAT products is significantly larger than current consumption indicates;
- the timing of, and our ability to, obtain and/or maintain regulatory approvals for our products and new product candidates, the rate and degree of market acceptance, and the clinical utility of our products;
- the expected timeline of our development program for our product candidates, including statements about clinical trials and regulatory milestone dates;
- our expectation of receiving top line results by late April or early May of 2014 for a Phase II/III clinical trial in Europe for our inhaled formulation of AAT for treatment of AAT deficiency ("Inhaled AAT for AATD");
- our goal, if we receive marketing authorization, to launch Inhaled AAT for AATD in 2015 in Europe and 2016 in the United States;
- our anticipation that we will generate higher revenues as we diversify our revenue base by increasing the number of products we offer;
- legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, access or distribution channels;

- the impact of geographic and product mix on our total revenues and gross profit; and
- the impact of our research and development expenses as we continue developing product candidates.

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All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of the expected results, depend on many events, some or all of which are not predictable or within our control. Actual results may differ materially from expected results. See the sections "Item 3. Key Information — D. Risk Factors," "Item 5. Operating and Financial Review and Prospectus" and elsewhere in this Annual Report for a more complete discussion of these risks, assumptions and uncertainties and for other risks and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results.

All of the forward-looking statements we have included in this Annual Report are based on information available to us on the date of this Annual Report. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur.

The audited consolidated financial statements for the years ended December 31, 2013, 2012 and 2011 in this Annual Report have been prepared in accordance with the international financial reporting standards ("IFRS") as issued by the international accounting standards board ("IASB"). None of the financial information in this Annual Report has been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following table summarizes our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2013, 2012 and 2011 and the consolidated balance sheets data as of December 31, 2013 and 2012 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the summary consolidated statements of operations data for the year ended December 31, 2010 and the summary consolidated balance sheet data as of December 31, 2010 from our audited consolidated financial statements not included in this Annual Report.

We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year.

The summary of our consolidated financial data set forth below should be read together with our consolidated financial statements and the related notes, as well as the section entitled “Item 5. Operating and Financial Review and Prospects,” included elsewhere in this Annual Report.

	Year Ended December 31,			
	2013	2012	2011	2010
	(in thousands, except per share data)			
Consolidated Statements of Operations Data:				
Revenues from Proprietary Products	$50,658	$46,445	$35,308	$22,980
Revenues from Distribution	19,965	26,230	24,175	11,497
Total revenues	70,623	72,675	59,483	34,477
Cost of revenues from Proprietary Products	27,104	26,911	22,188	18,878
Cost of revenues from Distribution	17,112	23,071	20,574	9,827
Total cost of revenues	44,216	49,982	42,762	28,705
Gross profit	26,407	22,693	16,721	5,772
Research and development expenses	12,745	11,821	11,729	9,279
Selling and marketing expenses	2,100	1,853	2,331	2,152
General and administrative expenses	7,862	4,781	5,126	4,543
Operating income (loss)	3,700	4,238	(2,465)	(10,202)
Financial income	289	578	870	560
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	(369)	(100)	937	(1,052)
	—	(576)	540	(640)

Income (expense) in respect of revaluation of warrants to fair value				
Financial expense	(3,153)	(3,357)	(3,597)	(3,087)
Income (loss) before taxes on income	467	783	(3,715)	(14,421)
Taxes on income	24	523	—	—
Net income (loss)	$443	$260	$(3,715)	$(14,421)
Income (loss) attributable to equity holders	$443	$260	$(3,715)	$(14,421)
Income (loss) per share attributable to equity holders:				
Basic	$0.01	$0.01	$(0.13)	$(0.54)
Diluted	$0.01	$0.01	$(0.15)	$(0.54)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:				
Basic	32,714,631	28,078,996	27,550,643	26,674,717
Diluted	33,385,651	28,686,636	27,703,331	26,674,717
Consolidated Statements of Cash Flows:				
Cash flows from operating activities	$(3,854)	$(8,262)	$994	$10,037
Cash flows from investing activities	(3,903)	(2,432)	(1,136)	(22,183)
Cash flows from financing activities	49,208	2,966	(403)	7,430
Consolidated Balance Sheet Data:				
Cash, cash equivalents, restricted cash and short-term investments	$74,177	$33,795	$42,686	$46,071
Trade receivables	17,882	13,861	7,131	12,827
Working capital (1)	85,108	40,651	44,185	51,545
Total assets	139,379	89,114	85,114	91,496
Total liabilities	49,409	60,721	62,716	65,172
Total shareholders' equity	89,970	28,393	22,398	26,324
Other Data:				
Adjusted net income (loss)(2) (3)	$9,414	$2,103	$(3,377)	$(12,161)
Adjusted EBITDA(2)	$3,156	$8,549	$1,453	$(5,941)

(1) Working capital is defined as total current assets minus total current liabilities.

(2) We present adjusted net income (loss) and adjusted EBITDA because we use these non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes these non-IFRS financial measures are useful to investors because: (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) they exclude the impact of non-cash items that are not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business.

Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described below, and we expect to continue to incur expenses similar to the non-cash, non-IFRS adjustments described below. Accordingly, unless otherwise stated, the exclusion of these and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted net income (loss) and adjusted EBITDA are not recognized terms under IFRS and do not purport to be an alternative to IFRS net income (loss) as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted net income (loss) or adjusted EBITDA may not be comparable to other similarly titled measures of other companies.

Adjusted net income (loss) is defined as net income (loss), plus non-cash share-based compensation expenses, plus a one-time management compensation payment associated with the successful U.S. initial public offering, and plus or minus expense or income in respect of revaluation of our warrants to fair value. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance. Our management believes that excluding the one-time management compensation payment associated with the successful U.S. initial public offering is useful to investors because of the extraordinary, non-recurring nature of the expense. Similarly, our management believes that excluding the non-cash income (expense) in respect of revaluation of our warrants to fair value is useful to investors because the valuation of our warrants is based on a number of subjective assumptions, the amount of the loss or gain is derived from market forces outside management's control, and it enables investors to compare our performance with other companies that have different capital structures. Additionally, the revaluation of the fair value of our warrants is not expected to recur in future periods after the first quarter of 2013, as the warrants were exercised in the first quarter of 2013.

(3) Adjusted EBITDA is defined as net income (loss), plus income tax expense, plus financial expense, net, plus depreciation and amortization expense, plus non-cash share-based compensation expenses, plus or minus income or expense in respect of exchange and translation differences and derivatives instruments not designated as hedging, plus or minus income or expense in respect of revaluation of our warrants to fair value, and plus one-time management compensation payment. Management believes that adjusted EBITDA provides useful information to investors for the same reasons discussed above for adjusted net income (loss).

The following tables set forth adjusted net income (loss) and adjusted EBITDA and also reconcile these figures to the IFRS measure net income (loss):

	Year Ended December 31,			
	2013	2012	2011	2010
	(in thousands)			
Net income (loss)	$443	$260	$(3,715)	$(14,421)

Non-cash share-based compensation expenses	1,327	1,267	878	1,620
One-time management compensation payment	1,386	—	—	—
Expense (income) in respect of revaluation of warrants to fair value	—	576	(540)	640
Adjusted net income (loss)	$3,156	$2,103	$(3,377)	$(12,161)

	Year Ended December 31,			
	2013	2012	2011	2010
	(in thousands)			
Net income (loss)	$443	$260	$(3,715)	$(14,421)
Income tax expense	24	523	—	—
Financial expense, net	2,864	2,779	2,727	2,528
Depreciation and amortization expense	3,001	3,044	3,040	2,640
Non-cash share-based compensation expenses	1,327	1,267	878	1,620
Income (expense) in respect of translation differences and derivatives instruments, net	369	100	(937)	1,052
Expense (income) in respect of revaluation of warrants fair value	—	576	(540)	640
One-time management compensation payment	1,386	—	—	—
Adjusted EBITDA	$9,414	$8,549	$1,453	$(5,941)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the consolidated financial statements and the related notes included elsewhere in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Our business is currently highly concentrated on our flagship product, Glassia, and our largest geographic region, the United States. Any adverse market event with respect to such product or the United States would have a material adverse effect on our business.

We rely heavily upon the sales of our AAT intravenous product, Glassia. Revenue from our intravenous AAT deficiency ("AATD") products comprised approximately 49%, 47% and 44% of our total revenues for the years ended December 31, 2013, 2012 and 2011, respectively. If Glassia were to lose significant sales, or was substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if Glassia were to become the subject of litigation and/or an adverse governmental ruling requiring us to cease sales of Glassia, our business would be adversely affected.

We have a partnership arrangement with Baxter International Inc., pursuant to which Baxter is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Revenue derived from our partnership with Baxter, which consists of sales of Glassia and milestone revenue, accounted for approximately 40%, 42% and 41% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively. Additionally, we depend upon Baxter for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. If our relationship with Baxter were to deteriorate, or if Baxter's sales of Glassia were to decline, our business would be adversely affected. See "In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability."

We rely heavily upon sales from the United States, which comprised approximately 41%, 43% and 41% of our total revenues for the years ended December 31, 2013, 2012 and 2011, respectively. If our U.S. sales were significantly impacted by either material changes to government or private payor reimbursement, by other regulatory developments, by competition or other factors, then our business would be adversely affected.

If we are unable to successfully introduce new products and indications or fail to keep pace with advances in technology, our business, financial condition and results of operations could be adversely affected.

We operate in highly innovative businesses. We currently rely on sales of Glassia for a significant portion of our total revenues. However, our continued growth depends in large part on our ability to develop and obtain approval of new products and new indications for our products and product candidates. In particular, obtaining approval of our Inhaled AAT for AATD from the European Medicines Agency (the "EMA") initially and the United States Food and Drug Administration (the "FDA") thereafter is critical to our business plan. Failure to obtain regulatory approval of the Inhaled AAT for AATD product or of any of our other product candidates or additional indications would materially adversely impact our business prospects.

The development of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

We may not be able to commercialize our product candidates in development for numerous reasons.

Before obtaining regulatory approval for the sale of our product candidates, including Inhaled AAT for AATD, or for the marketing of existing products for new indications, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We cannot predict how long the approval processes of the FDA, the EMA, the regulatory authorities in Israel or any other applicable regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA, the EMA, the regulatory authorities in Israel and other regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country.

Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site;

- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge among jurisdictions;

- delays may occur in obtaining our clinical materials;

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or to abandon strategic projects;

- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate or participants may withdraw from our clinical trials at higher rates than we anticipate, any of which would result in significant delays in our clinical testing process;

- delays may occur in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;

- our third-party contractors, such as a contract research organization, may fail to comply with regulatory requirements or meet their contractual obligations to us;

- we may be forced to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks or if any participant experiences an unexpected serious adverse event;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;

- the cost of our clinical trials may be greater than we anticipate;

- an audit of preclinical or clinical studies by the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities may reveal noncompliance with applicable regulations, which could lead to disqualification of the results and the need to perform additional studies; and

- our product candidates may not achieve the desired clinical benefits or may cause undesirable side effects, or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if safety concerns arise, we may:

- be delayed in obtaining marketing approval for our product candidates;

- decide to halt the clinical trial or other testing;

- be unable to obtain regulatory and marketing approval;

- be unable to obtain reimbursement for our products in some countries;

- obtain approval for indications that are not as broad as we intended;

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- have the product removed from the market after obtaining marketing approval from the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities; or

- be delayed in, or prevented from, receiving the receipt of clinical milestone payments from our strategic partners.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could lead to a shorter patent protection period during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do, impairing our ability to commercialize our products or product candidates. For example, in the past, we have experienced delays in the commencement of clinical trials, such as a delay in patient enrollment for our clinical trials in Europe for Inhaled AAT for AATD and a delay in receiving approval for the commencement of Phase II trials in the United States for Inhaled AAT for AATD until further preclinical testing results were submitted.

Even if preclinical trials are successful, we still may be unable to commercialize a product because of difficulties in obtaining regulatory approval for its engineering process or problems in scaling that process to commercial production.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, new indications for our AAT products that are entering into Phase I and II clinical trials may be found not to be safe and/or efficacious when studied further in Phase III trials. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase II trials, does not ensure that later clinical trials will be successful. Initial results from Phase I and II clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We cannot provide assurance that any products we may seek to develop or are currently developing, such as Inhaled AAT for AATD, will ever be successfully commercialized, and to the extent they are not successfully commercialized, such products could be a significant expense with no reward.

We may not obtain orphan drug status for our products, or we may lose orphan drug designations, which would have a material adverse effect on our business.

Many of our products and product candidates, including Inhaled AAT for AATD, have been granted the designation of an orphan drug. One of the incentives provided by an orphan drug designation is market exclusivity for seven years in the United States and ten years in the European Union for the first product in a class approved for the treatment of a rare disease. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. We may not be the first product licensed for the treatment of a rare disease. In such a situation, we would not be able to take advantage of market exclusivity and instead the other sponsor would receive such exclusivity. In the event we are unable to fill demand for any orphan drug, it is possible that the FDA or the EMA may view such unmet demand as a market shortage which could impact the market exclusivity. The FDA or the EMA may also, in the future, revisit any orphan drug designation it has conferred upon a drug and retains the ability to withdraw the designation at any time. Additionally, the U.S. Congress has considered, and may consider in the future, legislation that would restrict the

duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits to us of the existing statute will remain in effect.

The commercial success of any products that we may develop, if any, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenue and we may not sustain profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

- the prevalence and severity of any side effects;
- the efficacy, potential advantages and timing of introduction to the market of alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of physicians to prescribe our products;
- the willingness of patients to use our products;
- the strength of marketing and distribution support; and
- third-party coverage or reimbursement.

If we are not successful in achieving market acceptance for any new products that we have developed and have been approved for commercial sale, we may be unable to recover the large investment we have made and plan to make in research and development efforts and our growth strategy will be adversely affected.

Our products involve biological intermediates that are susceptible to contamination, which could adversely affect our operating results.

Plasma and its derivatives, such as fraction IV, are raw materials that are susceptible to damage and contamination and may contain microorganisms that cause diseases in humans, commonly known as human pathogens, any of which would render such materials unsuitable as raw material for further manufacturing. Almost immediately after collection from a donor, plasma and plasma derivatives must be stored and transported at temperatures that are at least -20 degrees Celsius (-4 degrees Fahrenheit). Improper storage or transportation of plasma or plasma derivatives by us or third-party suppliers may require us to destroy some of our raw material. In addition, plasma and plasma derivatives are also suitable for use only for certain periods of time once removed from storage. If unsuitable plasma or plasma derivatives are not identified and discarded prior to release to our manufacturing processes, it may be necessary to discard intermediate or finished products made from that plasma or plasma derivatives, or to recall any finished product released to the market, resulting in a charge to cost of goods sold and harm to our brand and reputation. Furthermore, if we distribute plasma-derived protein therapeutics that are produced from unsuitable plasma because we have not detected any contaminants or impurities, we could be subject to product liability claims and our reputation would be adversely affected.

Additionally, despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease-causing agents, the risk of transmissible disease through plasma-derived

protein therapeutics cannot be entirely eliminated. If a new infectious disease was to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to manufacture our products. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived protein therapeutics. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma or plasma derivatives used in the production of our plasma-derived protein therapeutics. Additionally, this could trigger the need for changes in our existing inactivation and production methods, including the administration of new detection tests, which could result in delays in production until the new methods are in place, as well as increased costs that may not be readily passed on to our customers.

Plasma and plasma derivatives can also become contaminated through the manufacturing process itself, such as through our failure to identify and purify the contaminant through our manufacturing process or failure to maintain a high level of sterility within our manufacturing facilities.

Once we have manufactured our plasma-derived protein therapeutics, they must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship, store or distribute our products, to properly care for our plasma-derived products, may result in the requirement that such products be destroyed.

While we expect to write off small amounts of work-in-process inventories in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived protein therapeutics, unanticipated events may lead to write-offs and other costs materially in excess of our expectations. We had in the past situations that have caused us to write off the value of our product. For example, in the past year we have had to discard an immaterial amount of inventory that did not pass our inspections due to deviations in the production process that had created a higher risk of contamination. Such write-offs and other costs could cause material fluctuations in our operating results. Furthermore, contamination of our plasma-derived protein therapeutics could cause consumers or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect sales and operating results.

Our ability to continue manufacturing and distributing our plasma-derived protein therapeutics depends on our continued adherence to cGMP regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that set forth current Good Manufacturing Practice standards (“cGMP”) requirements for blood products, including plasma and plasma derivative products. Failure by our quality operations unit to adhere to established procedures or regulations, or to meet a specification set forth in cGMP requirements, could require that a product or material be rejected and destroyed. There are relatively few opportunities for us to rework, reprocess or salvage nonconforming materials or products. Our manufacturing process and facilities are not currently approved by the EMA, and we will need to obtain such approval prior to beginning manufacture of products (including Inhaled AAT for AATD) to be marketed and sold in Europe.

Our adherence to cGMP regulations and the effectiveness of our quality control systems are periodically assessed through inspections of our manufacturing facility in Beit Kama, Israel by the FDA and regulatory authorities of other countries. Such inspections could result in deficiency citations, which would require us to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we are unable to prevent recurrences, we may have to recall products or suspend operations until appropriate measures can be implemented. We are required to report certain deviations from procedures to the FDA. Even if we determine that the deviations were not material, the FDA could require us to take certain measures to address the deviations. Since cGMP reflects ever-evolving standards, we regularly need to update our manufacturing processes and procedures to comply with cGMP. These changes may cause us to incur additional costs and may adversely impact our profitability. For example, more sensitive testing assays (if and when they become available) may be required or existing procedures or processes may require revalidation, all of which may be costly and time-consuming and could delay or prevent the manufacturing of a product or launch of a new product.

The biologic properties of plasma and plasma derivatives are variable, which may adversely impact our levels of product yield from our plasma or plasma derivative supply.

Due to the nature of plasma, there will be variations in the biologic properties of the plasma or plasma derivatives we purchase that may result in fluctuations in the obtainable yield of desired fractions, even if cGMP is followed. Lower yields may limit production of our plasma-derived protein therapeutics because of capacity constraints. If these batches of plasma with lower yields impact production for extended periods, we may not be able to fulfill orders on a timely basis and the total capacity of product that we are able to market could decline and our cost of goods sold could increase, thus reducing our profitability.

Usage of our products may lead to serious and unexpected side effects, which could materially adversely affect our business and may, among other factors, lead to our products being recalled and our reputation being harmed, resulting in an adverse effect on our operating results.

As with many pharmaceutical products, the use of our plasma-derived protein therapeutics may produce undesirable side effects or adverse reactions or events. For the most part, these side effects are known, are expected to occur at some frequency and are described in the products' labeling. Known side effects of a number of our plasma-derived protein therapeutics include headache, nausea and additional common protein infusion related events such as flu-like symptoms, dizziness and hypertension. The occurrence of known side effects on a large scale could adversely affect our reputation and public image, and hence also our operating results.

In addition, the use of our plasma-derived protein therapeutics may be associated with serious and unexpected side effects, or with less serious reactions at a greater than expected frequency. This may be especially true when our products are used in critically ill patient populations. When these unexpected events are reported to us, we typically make a thorough investigation to determine causality and implications for product safety. These events must also be specifically reported to the applicable regulatory authorities. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with one of our products, we would be obligated to withdraw the impacted lot or lots of that product or, in certain cases, to withdraw the product entirely. Furthermore, it is possible that an unexpected side effect caused by a product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation.

We are subject to a number of existing laws and regulations in multiple jurisdictions, non-compliance with which could adversely affect our business, financial condition and results of operations, and we are susceptible to a changing regulatory environment which could increase our compliance costs or reduce profit margins.

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and similar authorities in other jurisdictions, including the EMA and the regulatory authorities in Israel. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or similar authorities in other jurisdictions, including a failed inspection or a failure in our reporting system for adverse effects of our products experienced by the users of our products, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. In addition, we rely to a large extent on Baxter for purposes of most of our regulatory compliance for Glassia and product development and approvals in the United States relating to Glassia. Any failure by Baxter to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements could adversely affect us. If our relationship with Baxter terminated for any reason, we may be unable to maintain regulatory compliance on a cost-effective basis, if at all. Any of these actions could cause direct liabilities, a loss in our ability to market Glassia, or a loss of customer confidence in us or Glassia, which could adversely affect our sales, reputation, and results of

operations.

Any changes in our production processes for our products must be approved by the FDA and/or similar authorities in other jurisdictions. Failure to comply with any requirements as to production process changes dictated by the FDA or similar authorities in other jurisdictions could also result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Recently, as part of our on-going effort to increase efficiency and profitability, we submitted a supplement with the FDA to make changes to the production processes for Glassia, which are intended to scale-up the output of our manufacturing facility and began to produce Glassia using the improved processes. In March 2013, we received a request from the FDA to submit additional data and explanations prior to its approval of our new production processes. We have recently provided the additional information required by the FDA and expect to receive the FDA approval during the third quarter of 2014. While such FDA review is pending, we are continuing to produce Glassia according to FDA-approved production processes. We cannot provide assurances that we will obtain approval for the improved processes on a timely basis or at all. Failure to obtain such approval, or obtaining approval only on a prospective basis, could cause us to write off the value of the inventory produced using the new methods. Delays in obtaining such approval could delay revenues from Baxter or Glassia. In addition, we would not obtain the margin benefits we are anticipating from such new operating processes and could have difficulty meeting increased demand in the future.

In addition, changes in the regulation of our activities, such as increased regulation affecting safety requirements or new regulations such as limitations on the prices charged to customers in the European Union, the United States, Israel or other jurisdictions in which we operate, could materially adversely affect our business. In addition, the requirements of different jurisdictions in which we operate may become less uniform, creating a greater administrative burden and generating additional compliance costs, which would have a material adverse effect on our profit margins.

We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements.

Our products that generate the majority of our revenues depend on our access to U.S. or European source plasma or its derivative, fraction IV. Our plasma and fraction IV are purchased from third-party licensed suppliers which are also responsible for the fractionation process, pursuant to multiple purchase agreements. We have entered into a number of supply agreements with various third parties in the United States and Europe, some of which are also strategic partners in the distribution of our proprietary products. These agreements contain various termination provisions, including upon a material breach of either party, force majeure and, with respect to supply agreements with strategic partners, the failure or delay on the part of either party to obtain the applicable regulatory approvals or the termination of the principal strategic relationship. If we are unable to obtain adequate quantities of source plasma or fraction IV approved by the FDA, the EMA or the regulatory authorities in Israel from these providers, we may be unable to find an alternative cost-effective source.

In order for plasma and fraction IV to be used in the manufacturing of our plasma-derived protein therapeutics, the individual centers at which the plasma is collected must be licensed and approved by the relevant regulatory authorities, such as the FDA or the EMA. When a new plasma collection center is opened, and on an ongoing basis after its licensure, it must be inspected by the FDA and the EMA and the regulatory authorities in Israel for compliance with cGMP and other regulatory requirements. An unsatisfactory inspection could prevent a new center from being licensed or lead to the suspension or revocation of an existing license. If we or relevant regulatory authorities determine a plasma collection center did not comply with cGMP in collecting plasma, we may be unable to use and may ultimately destroy plasma collected from that center, which may impact on our ability to timely meet our manufacturing and supply obligations. Additionally, if noncompliance in the plasma collection process is identified

after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs which could adversely affect our business and financial results.

In addition, the plasma supplier's fractionation process must also meet standards of the FDA, the EMA and the regulatory authorities in Israel. If a plasma supplier is unable to meet such standards, we will not be able to use the plasma derivatives provided by such supplier, which may impact on our ability to timely meet our manufacturing and supply obligations.

If we were unable to obtain adequate quantities of source plasma or plasma derivatives approved by the FDA, the EMA or the regulatory authorities in Israel, we would be limited in our ability to maintain or increase current manufacturing levels of our plasma derivative products, as well as our ability to conduct the research required to maintain a robust product pipeline. As a result, we could experience a substantial decrease in total revenues or profit margins, a potential breach of distribution agreements, a loss of customers, a negative effect on our reputation as a reliable supplier of plasma derivative products or a substantial delay in our production and strategic growth plans.

The ability to increase plasma collections may be limited, our supply of plasma and plasma derivatives could be disrupted or the cost of plasma and plasma derivatives could increase substantially, as a result of numerous factors, including a reduction in the donor pool, increased regulatory requirements, decreased number of plasma supply sources due to consolidation and new indications for plasma-derived protein therapeutics, which could increase demand for plasma and plasma derivatives and lead to shortages.

We are also dependent on a number of suppliers who supply specialty ancillary products used in the production process, such as specific gels and filters. Each of these specialty ancillary products is provided by a single, exclusive supplier. If these suppliers were unable to provide us with these specialty ancillary products or if our relationships with these suppliers deteriorate, the production of our products would be materially adversely affected, which would adversely affect our sales and results of operations.

In addition, regulatory requirements, including cGMP regulations, continually evolve. Failure of our plasma suppliers to adjust their operations to conform to new standards as established and interpreted by applicable regulatory authorities would create a compliance risk that could impair our ability to sustain normal operations.

We have been required to conduct post-approval clinical trials of Glassia as a condition to marketing the product in the United States, and we may be required to conduct post-approval clinical trials as a condition to licensing or distributing other products.

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase IV clinical trials. For example, the FDA has required that we conduct Phase IV clinical trials of Glassia. The trials are aimed at collecting additional safety data, such as the immune response in the body of a human or animal, commonly referred to as immunogenicity, viral transmission, levels of the protein in the lung, or epithelial lining fluid, and certain efficacy endpoints requested by the FDA. If the results of such trials are unfavorable and demonstrate a previously undetected risk or provide new information that puts the patients at risk, this could result in the loss of the approval to market the product in the United States and other countries, or the imposition of restrictions, such as additional labeling, with a resulting loss of sales. Other products we develop may face similar requirements, which would require additional resources and which may not be successful.

The nature of producing plasma-derived protein therapeutics may prevent us from responding in a timely manner to market forces and effectively managing our production capacity.

The production of plasma-derived protein therapeutics is a lengthy and complex process. Our ability to match our production of plasma-derived protein therapeutics to market demand is imprecise and may result in a failure to meet the market demand for our plasma-derived protein therapeutics or potentially in an oversupply of inventory. Failure to meet market demand for our plasma-derived protein therapeutics may result in customers transitioning to available

competitive products, resulting in a loss of segment share or customer confidence. In the event of an oversupply in the market, we may be forced to lower the prices we charge for some of our plasma-derived protein therapeutics, record asset impairment charges or take other action which may adversely affect our business, financial condition and results of operations.

In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability.

Pursuant to our partnership arrangement with Baxter, Baxter is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Sales to Baxter accounted for approximately 40%, 42% and 41% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively. We also depend upon Baxter for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. See "—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements."

Currently, revenue derived from our relationship with Baxter consists of sales of Glassia, which we incur cost of revenues to produce, and milestone revenue. After 2016, Baxter has no obligation to purchase a minimum amount of Glassia; however, Baxter's failure to purchase a specified minimum amount of Glassia over a period of 24 consecutive months beginning in 2016 until the expiration of the agreement provides us with the right to terminate the agreement. Additionally, Baxter is expected to begin producing Glassia itself in 2017 at the earliest, at which point it will pay us royalties. While we would generate higher margins from royalties, as we would not incur cost of revenues, we will receive lower revenues per unit sold. We plan to replace that revenue by producing other AAT products, including for sales in Europe, and increases in the volume of units sold. If we could not obtain approval and make such sales in Europe or were unable to increase sales of our products, our revenues would be impacted and our operating results would be impacted as we would continue to incur the fixed costs relating to our manufacturing facility.

In addition, for Inhaled AAT for AATD, we intend to rely on our relationship with Chiesi for the distribution of Inhaled AAT for AATD in Europe and to obtain reimbursement for our Inhaled AAT for AATD product in Europe. Chiesi's failure to adequately distribute or to obtain reimbursement will have a material adverse effect on our expected profitability from sales of Inhaled AAT for AATD in Europe.

If our relationship with Baxter were to deteriorate, our sales through this channel and our supply of fraction IV could be adversely affected. If we fail to maintain our relationship with Baxter or Chiesi, we could face significant costs in finding a replacement distributor for the markets Baxter and Chiesi serve for Glassia and Inhaled AAT for AATD, respectively, and a replacement supplier of fraction IV for Glassia. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Each inhaled formulation of AAT, including Inhaled AAT for AATD, is being developed with a specific nebulizer produced by PARI, and the occurrence of an adverse market event or PARI's non-compliance with its obligations would have a material adverse effect on the commercialization of any inhaled formulation of AAT.

We are dependent upon PARI for the commercialization of any inhaled formulation of AAT, including our second generation AATD product, Inhaled AAT for AATD. We have an agreement with PARI, pursuant to which it is required to obtain the appropriate clearance to market PARI's eFlow device, which is a device required for the administration of inhaled formulation of AAT, from the EMA and FDA for use with Inhaled AAT for AATD. See "Item 4. Information on the Company — Strategic Partnerships — PARI." Failure of PARI to achieve these authorizations will have a material adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD, which would harm our growth strategy.

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Additionally, pursuant to the agreement, PARI is obligated to manufacture and supply all of the market demand for the eFlow device for use in conjunction with any inhaled formulation of AAT and we are required to purchase all of our volume requirements from PARI. Any event which permanently, or for an extended period, prevents PARI from supplying the required quantity of devices would have an adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD.

Our Distribution segment is dependent on a few suppliers, and any disruption to our relationship with these suppliers, or their inability to supply us with the products we sell, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.

Sales of products supplied by Bioproducts Laboratories Ltd. and Biotest A.G., which are sold in our Distribution segment, together represented approximately 26%, 35% and 39% of our total revenues for the years ended December 31, 2013, 2012 and 2011, respectively. While we have distribution agreements with each of these suppliers, these agreements do not obligate these suppliers to provide us with minimum amounts of our Distribution segment products. Purchases of our Distribution segment products from our suppliers are typically on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts are not obligations or commitments. However, if we fail to submit purchase orders that meet our annual forecasts, we could lose exclusivity or the agreement could be terminated. These suppliers may experience capacity constraints that result in their being unable to supply us with products in a timely manner, in adequate quantities and/or at a reasonable cost. Contributing factors to supplier capacity constraints include, among other things, industry or customer demands in excess of machine capacity, labor shortages and changes in raw material flows. These suppliers may also choose not to supply us with products at their discretion or raise prices to a level that would render our products noncompetitive. Any significant interruption in the supply of these products could result in us being unable to meet the demands of our customers, which would have a material adverse effect on our business, financial condition and results of operations.

Additionally, if our relationship with either were to deteriorate, our distribution sales could be adversely affected. If we fail to maintain our existing relationships with these suppliers, we could face significant costs in finding a replacement supplier, and delays in establishing a relationship with a new supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors.

Our business requires substantial capital, including potential investments in large capital projects, to operate and grow and to achieve our strategy of realizing increased operating leverage.

In order to obtain FDA, EMA and other regulatory approval for product candidates and new indications for existing products, we are required to enhance the facilities in which and processes by which we manufacture existing products, to develop new product delivery mechanisms for existing products and to develop innovative product additions and conduct clinical trials. We face a number of obstacles that we will need to overcome in order to achieve these goals, including but not limited to the successful development of an experimental product for use in clinical trials, the design of clinical study protocols acceptable to the FDA, the EMA and other regulatory authorities, the successful outcome of clinical trials, scaling our manufacturing processes to produce commercial quantities or successfully transition technology, obtaining FDA, EMA and other regulatory approvals of our products or processes and successfully marketing an approved product or new product with our new process. To finance these various activities, we may need to incur future debt or issue additional equity, and we may not be able to structure our debt obligations on favorable economic terms. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

In addition, any enhancements to our manufacturing facilities necessary to obtain FDA or EMA approval for product candidates or new indications for existing products could require large capital projects. We may also undertake such capital projects in order to maintain compliance with cGMP or expand capacity. Capital projects of this magnitude involve technology and project management risks. Technologies that have worked well in a laboratory or in a pilot plant may cost more or not perform as well, or at all, in full scale operations. Projects may run over budget or be delayed. We cannot be certain that these projects will be completed in a timely manner or that we will maintain our compliance with cGMP, and we may need to spend additional amounts to achieve compliance. Additionally, by the time these multi-year projects are completed, market conditions may differ significantly from our assumptions regarding competitors, customer demand, alternative therapies, reimbursement and public policy, and as a result capital returns may not be realized. A failure to invest in large capital projects may harm our competitive position and financial condition. In addition, to fund large capital projects, we may need to incur future debt or issue additional equity, and we may not be able to structure our debt obligations on favorable economic terms. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our Proprietary Products segment operates in a highly competitive market.

We compete with well-established drug companies, including two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd., Baxter, Cangene Corporation and Grifols S.A., which acquired a previous competitor, Talecris Biotherapeutics, Inc., in 2011. We compete against these companies for, among other things, licenses, expertise, clinical trial patients and investigators, consultants and third-party strategic partners. We also compete with these companies for market share for certain products in the Proprietary Products segment. Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. As a result, they may be able to devote more funds to research and development and new production technologies, as well as to the promotion of their products and business. These competitors may also be able to sustain for longer periods a deliberate substantial reduction in the price of their products or services. Some of them also have an additional advantage regarding the availability of raw materials, as they manufacture plasma and its products, and own companies that collect or produce raw materials such as plasma. Other than our AAT products, our products generally do not benefit from patent protection and compete against similar products produced by other providers.

Additionally, the development by a competitor of a similar or superior product or increased pricing competition may result in a reduction in our net sales or a decrease in our profit margins.

For example, we believe that there are two main competitors in the AAT market: Grifols and CSL. We estimate that Grifols's AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for more than 70% of sales in the worldwide market for the treatment of AATD, and is the only product that is allowed to be sold in both Europe and the United States. Due to its limited availability, CSL's product is mainly sold in the United States. Apart from its sales through Talecris, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. There is another, smaller local producer in the French market, LFB S.A.

Similarly, if a new AAT formulation with a significantly improved rate of administration is adopted (including, for example, aerosol inhalation or one that can demonstrate statistically significant efficacy), the market share of our current AAT product, Glassia, could be negatively impacted. While we are in the process of developing Inhaled AAT for AATD, our competitors may also be attempting to develop similar products or products which could be substitutions for AAT products, such as gene therapy. For example, Grifols recently completed a limited clinical trial for the development of an inhaled formulation of AAT for the indication of cystic fibrosis. While we believe that these products are in the early stages of development, they may eventually be successfully developed and launched. Furthermore, even if we are able to commercialize Inhaled AAT for AATD prior to the development of comparable

products by our competitors, sales of Inhaled AAT for AATD could adversely impact our revenue and growth of sales of Glassia, our current AATD product.

In addition, our plasma-derived protein therapeutics face competition from existing non-plasma products and other courses of treatments. For example, we believe our main competitor for KamRho(D) (IM and IV) is Kedrion, which in 2012 acquired the Anti-Rh product line of Ortho-Clinical Diagnostics, Inc., formerly our main competitor for KamRho(D) (IM or IV). Kedrion sells a product that we estimate accounts for approximately 50% of sales in the U.S. anti-Rh market. We believe there are three additional competitors in this market: Cangene, Grifols and CSL. Additionally, in 2008, GlaxoSmithKline plc and Amgen Inc. launched thrombopoietin inhibitors targeting immune thermobocytopunic purpura patients, which may reduce the demand for intravenous immunoglobulins ("IVIG") to treat immune thermobocytopunic purpura. New treatments, such as small molecules, monoclonal or recombinant products, may also be developed for indications for which our products are now used. We do not currently sell any recombinant products. We have begun developing recombinant versions of AAT, but we cannot be certain that such products will ever be approved or commercialized. The main advantage of recombinant AAT is its potentially higher availability at lower price per raw material. As a result, our product offerings may remain plasma-derived, even if our competitors offer competing recombinant or other non-plasma products or treatments.

Sales in our Distribution segment rely primarily on our ability to win tender bids based on the price and availability of our products in annual public tender processes.

We primarily sell our Distribution segment products through offers to participate in public tenders, which occur on an annual basis. The public tender process involves health maintenance organizations and hospitals soliciting bids from several potential suppliers, including us, and selecting the winning bid based on several attributes, primarily price and availability. The annual public tender process is also used by our existing customers to determine their suppliers. As a result, our existing relationships with customers in our Distribution segment do not guarantee additional orders from such customers year to year.

In 2010 through 2012, we benefitted from the temporary suspension of two of our competitors from selling their IVIG products in Israel. This suspension has been lifted and both competitors are now able to distribute plasma-derived protein therapeutics in the Israeli market. As these competing IVIG products returned to the market at the end of 2012, we have experienced increased competition for our Distribution segment products. For example, we recently participated in a public tender in Israel with these competitors. During this public tender process, some of our customers in prior years chose to purchase their supply requirements from our competitors. As a result of these competitors returning to the market, revenues from our Distribution segment decreased in 2013 and may further decrease in the future. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the annual tender process will be materially affected, and could reduce our total revenues or decrease our profit margins.

Certain of our products have historically been, and may in the future be, subject to supply-driven price fluctuations.

Certain of our products in both segments have historically been subject to price fluctuations as a result of changes in the production capacity available in the industry, the availability and pricing of plasma, development of competing products and the availability of alternative therapies. Higher prices for plasma-derived protein therapeutics have traditionally spurred increases in plasma production and collection capacity, resulting over time in increased product supply and lower prices. As demand continues to grow, if plasma supply and manufacturing capacity do not commensurately expand, prices tend to increase. Additionally, consolidation in plasma companies has led to a decrease in the number of plasma suppliers in the world, as either manufacturers of plasma-based pharmaceuticals purchase plasma suppliers or plasma suppliers are shut down in response to the number of manufacturers of plasma-based pharmaceuticals decreasing, which may lead to increased prices. We may not be able to pass along these increased plasma and plasma-derivative prices to our customers, which would reduce our profit margins.

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Sales of our Distribution segment products are made through public tenders of Israeli hospitals and health maintenance organizations on an annual basis. The prices we can offer, as well as the availability of products, are key factors in the tender process. If our suppliers in the Distribution segment cannot sell us products at a competitive price or cannot guarantee sufficient quantities of products, we may lose the tenders.

Product liability claims or product recalls involving our products or products we distribute could have a material adverse effect on our business.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution and sale of plasma-derived therapeutic protein products and other drug products. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk when we commercially sell any products including those manufactured by others that we distribute in Israel. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, or any indemnities we have negotiated do not cover any losses, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our plasma-derived protein therapeutics and any product candidates that we may develop;
- injury to our reputation;
- difficulties in recruitment of new participants to our future clinical trials and withdrawal of current clinical trials' participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- difficulties in finding distributors to our products;
- difficulties in entering strategic partnerships with third parties;
- diversion of management's attention;
- loss of revenue;
- the inability to commercialize any products that we may develop; and
- higher insurance premiums.

Plasma is biological matter that is capable of transmitting viruses and pathogens, whether known or unknown. Therefore, plasma derivative products, if not properly tested, inactivated, processed, manufactured, stored and transported, could cause serious disease and possibly death to the patient. Further, even when such steps are properly effected, viral and other infections may escape detection using current testing methods and may not be susceptible to inactivation methods. Any transmission of disease through the use of one of our products or third-party products sold by us could result in claims against us by persons allegedly infected by such products.

In addition, we sell and distribute third-party products in Israel, and the laws of Israel could also expose us to product liability claims for those products. Furthermore, the presence of a defect in a product could require us to carry out a recall of such product. A product liability claim or a product recall could result in substantial financial losses, negative

reputational repercussions and an inability to retain customers. Although we maintain insurance for certain types of losses, claims made against our insurance policies could exceed our limits of coverage or be outside our scope of coverage. Additionally, as product liability insurance is expensive and can be difficult to obtain, a product liability claim could increase our required premiums or otherwise decrease our access to product liability insurance on acceptable terms. In turn, we may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

Regulatory approval for our products is limited by the FDA and similar authorities in other jurisdictions to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the prescription or promotion of off-label uses could adversely affect our business.

Any regulatory approval of our products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA or similar authorities in other jurisdictions. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. Once we produce a plasma-derived protein therapeutic, we rely on physicians to prescribe and administer it as we have directed and for the indications described on the labeling. It is not, however, unusual for physicians to prescribe medication for unapproved, or "off-label," uses or in a manner that is inconsistent with the manufacturer's directions. To the extent such off-label uses and departures from our administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenues or potential revenues, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution.

The loss of one or more of our key employees could harm our business.

We depend on the continued service and performance of our key employees, including David Tsur, our Chief Executive Officer, and our other senior management. We have entered into employment agreements with all of our senior management, including Mr. Tsur, and other key employees. Either party, however, can terminate these agreements for any reason. The loss of key members of our executive management team could disrupt our operations or product development and have an adverse effect on our ability to grow our business.

Our ability to attract, recruit, retain and develop qualified employees is critical to our success and growth.

We compete in a market that involves rapidly changing technological and regulatory developments that require a wide ranging set of expertise and intellectual capital. In order for us to successfully compete and grow, we must attract, recruit, retain and develop the necessary personnel who can provide the needed expertise across the entire spectrum of our intellectual capital needs. While we have a number of our key personnel who have substantial experience with our operations, we must also develop our personnel to provide succession plans capable of maintaining continuity in the midst of the inevitable unpredictability of human capital. However, the market for qualified personnel is competitive, and we may not succeed in recruiting additional personnel, retaining current personnel or effectively replacing current personnel who depart with qualified or effective successors. Many of the companies with which we compete for experienced personnel have greater resources than us.

Our effort to retain and develop personnel may also result in significant additional expenses, which could adversely affect our profitability. We cannot assure that qualified employees will continue to be employed or that we will be able to attract and retain qualified personnel in the future. Failure to retain or attract key personnel could have a material adverse effect on our business, financial condition and results of operations.

We are subject to risks associated with doing business globally.

Our operations are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government and public tenders that are held annually in many cases, nationalization, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of applicable laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act of 2010, pricing restrictions, economic and political instability, disputes between countries, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition or results of operations.

We are subject to foreign currency exchange risk.

We receive payment for our sales and make payments for resources in a number of different currencies. While our sales and expenses are primarily denominated in U.S. dollars, our financial results may be adversely affected by fluctuations in currency exchange rates as a portion of our sales and expenses are denominated in other currencies, including the NIS and the Euro. Market volatility and currency fluctuations may limit our ability to cost-effectively hedge against our foreign currency exposure and, in addition, our ability to hedge our exposure to currency fluctuations in certain emerging markets may be limited. Hedging strategies may not eliminate our exposure to foreign exchange rate fluctuations and may involve costs and risks of their own, such as devotion of management time, external costs to implement the strategies and potential accounting implications. Foreign currency fluctuations, independent of the performance of our underlying business, could lead to materially adverse results or could lead to positive results that are not repeated in future periods.

Events in global credit markets may impact our ability to obtain financing or increase the cost of future financing or refinancing of our existing debt, including interest rate fluctuations based on macroeconomic conditions that are beyond our control.

As of December 31, 2013, we had total debt of approximately $16.2 million, which consists of convertible debentures. Fifty percent of this debt is due for repayment at the end of 2014, and this amount may be difficult to refinance or we may be required to refinance such debt at higher costs. During periods of volatility and disruption in the U.S., European, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt or replacing our existing convertible debentures could be higher than the costs we incur under our current debentures. The higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us. Additionally, our convertible debentures have a variable interest rate. By its nature, a variable interest rate will move up or down based on changes in the economy and other factors, all of which are beyond our control. If interest rates increase, our interest expense could increase, affecting earnings and reducing cash flows available for working capital, capital expenditures and acquisitions.

Developments in the economy may adversely impact our business.

Our operating and financial performance may be adversely affected by a variety of factors that influence the general economy in the United States, Europe and worldwide, including the current global economic slowdown and the ongoing challenges faced by European banks and the markets for the sovereign debt of certain European countries. Throughout many of our largest markets, including the United States and Europe, there have been dramatic declines in the housing market, high levels of unemployment and underemployment, and reduced earnings, or, in some cases, losses, for businesses across many industries, with reduced investments in growth.

A recessionary economic environment may adversely affect demand for our plasma-derived protein therapeutics. As a result of their job losses, patients in the U.S. may lose medical insurance and be unable to purchase needed medical products or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which purchase our products at a lower government price. A recessionary economic environment may also lead to price pressure for reimbursement of new drugs, which may adversely affect the demand for our future plasma-derived protein therapeutics.

If our manufacturing facility in Beit Kama, Israel were to suffer a serious accident, or if a force majeure event materially affected our ability to operate and produce saleable plasma-derived protein therapeutics, all of our manufacturing capacity could be shut down for an extended period.

We rely on a single manufacturing facility in Beit Kama, which is located in southern Israel approximately 20 miles from the Gaza Strip. All of our revenues in our Proprietary Products segment are derived from products manufactured at this facility. If this facility were to suffer an accident or a force majeure event such as war, terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of our backup generators or similar event, our revenues would be materially adversely affected. In this situation, our manufacturing capacity could be shut down for an extended period, we could experience a loss of raw materials, work in process or finished goods inventory and our ability to operate our business would be harmed. In addition, in any such event, the reconstruction of our manufacturing facility and storage facilities, and the regulatory approval of the new facilities could be time-consuming. During this period, we would be unable to manufacture our plasma-derived protein therapeutics.

Our insurance against property damage and business interruption insurance may be insufficient to mitigate the losses from any such accident or force majeure event. We may also be unable to recover the value of the lost plasma or work-in-process inventories, as well as the sales opportunities from the products we would be unable to produce, or the loss of customers during such period.

If we experience equipment difficulties or if the suppliers of our equipment or disposable goods fail to deliver key product components or supplies in a timely manner, our manufacturing ability would be impaired and our product sales could suffer.

For certain equipment and supplies, we depend on a limited number of companies that supply and maintain our equipment and provide supplies such as chromatography resins, filter media, glass bottles and stoppers used in the manufacture of our plasma-derived protein therapeutics. If our equipment were to malfunction, or if our suppliers stop manufacturing or supplying such machinery, equipment or any key component parts, the repair or replacement of the machinery may require substantial time and cost, and could disrupt our production and other operations. Alternative sources for key component parts or disposable goods may not be immediately available. In addition, any new equipment or change in supplied materials may require revalidation by us or review and approval by the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities, which may be time-consuming and require additional capital and other resources. We may not be able to find an adequate alternative supplier in a reasonable time period, or on commercially acceptable terms, if at all. As a result, shipments of affected products may be limited or delayed. Our inability to obtain our key source supplies for the manufacture of products may require us to delay shipments of products, harm customer relationships and force us to curtail operations.

If our shipping or distribution channels were to become inaccessible due to an accident, an act of terrorism, a strike or any other force majeure event, our supply, production and distribution processes could be disrupted.

Our raw materials must be transported at a temperature of -20 degrees Celsius (-4 degrees Fahrenheit) to ensure the preservation of their proteins. Not all shipping or distribution channels are equipped to transport plasma at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, an act of terrorism, a strike or any other force majeure event, we may experience disruptions in our continued supply of plasma and other raw materials, delays in our production process or a reduction in our ability to distribute our plasma-derived protein therapeutics to our customers.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property relating to or incorporated into our technology and products, including the patents protecting our manufacturing process.

Our success depends in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products, especially intellectual property related to our manufacturing processes. At present, we consider our two patents relating to our manufacturing process to be material to the operation of our business as a whole.

However, the patent landscape in the biotechnology and pharmaceutical fields is highly uncertain and involves complex legal, factual and scientific questions, and changes in either patent laws or in the interpretation of patent laws in the United States and other countries may diminish the value and strength of our intellectual property or narrow the scope of our patent protection. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of our process by third parties. Even if patents are issued to us or to our licensors, they may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to prevent competitors from using similar technology or marketing similar products, or limit the length of time our technologies and products have patent protection. Additionally, many of our patents relate to the processes we use to produce our products, not to the products themselves. In many cases, the plasma-derived products we produce or develop in the future will not, in and of themselves, be patentable. Since many of our patents relate to processes, if a competitor is able to utilize a process that does not rely on our protected intellectual property, that competitor could sell a plasma-derived product similar to one we developed or sell it without infringing these patents. In addition, we are a party to certain license agreements which may impose various obligations upon us as a licensee, including the obligation to make milestone and royalty payments. If we fail to comply with these obligations, the licensor may terminate the license, in which event we might not be able to market any product that is covered by the licensed intellectual property.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after their filing, if at all, and because publications of discoveries in scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in such patent applications. As a result, the patents we own and license may be invalidated in the future, and the patent applications we own and license may not be granted. For example, if a third party has also filed a patent application covering an invention similar to one covered in one of our patent applications, we may be required to participate in an adversarial proceeding, known as an “interference proceeding,” declared by the U.S. Patent and Trademark Office or its foreign counterparts to determine priority of invention. The costs of these proceedings could be substantial and our efforts in them could be unsuccessful, resulting in a loss of our anticipated patent position. In addition, if a third party prevails in such a proceeding and obtains an issued patent, we may be prevented from practicing technology or marketing products covered by that patent. Additionally, patents and patent applications

owned by third parties may prevent us from pursuing certain opportunities such as entering into specific markets or developing or commercializing certain products. Finally, we may choose to enter into markets where certain competitors have patents or patent protection over technology that may impede our ability to compete effectively.

Our patents expire at various dates between 2018 and 2027. However, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Our pending and future patent applications may not lead to the issuance of patents or, if issued, the patents may not be issued in a form that will provide us with any competitive advantage. We also cannot guarantee that: any of our present or future patents or patent claims or other intellectual property rights will not lapse or be invalidated, circumvented, challenged or abandoned; our intellectual property rights will provide competitive advantages or prevent competitors from making or selling competing products; our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes will not be limited by our agreements with third parties; any of our pending or future patent applications will be issued or have the coverage originally sought; our intellectual property rights will be enforced in jurisdictions where competition may be intense or where legal protection may be weak; or we will not lose the ability to assert our intellectual property rights against, or to license our technology to, others and collect royalties or other payments. In addition, our competitors or others may design around our patents or protected technologies. Effective protection of our intellectual property rights may also be unavailable, limited or not applied in some countries, and even if available, we may fail to pursue or obtain necessary intellectual property protection in such countries. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents and other intellectual property rights, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. Such lawsuits could entail significant costs to us and divert our management’s attention from developing and commercializing our products. Lawsuits may ultimately be unsuccessful, and may also subject us to counterclaims and cause our intellectual property rights to be challenged, narrowed, invalidated or held to be unenforceable.

Additionally, unauthorized use of our intellectual property may have occurred or may occur in the future, including, for example, in the production of counterfeit versions of our products. Counterfeit products may use different and possibly contaminated sources of plasma and other raw materials, and the purification process involved in the manufacture of counterfeit products may raise additional safety concerns, over which we have no control. Although we have taken steps to minimize the risk of unauthorized uses of our intellectual property, including for the production of counterfeit products, any failure to identify unauthorized use of, and otherwise adequately protect, our intellectual property could adversely affect our business, including reducing the demand for our products. Additionally, any reported adverse events involving counterfeit products that purport to be our products could harm our reputation and the sale of our products in particular and consumer willingness to use plasma-derived therapeutics in general. Moreover, if we are required to commence litigation related to unauthorized use, whether as a plaintiff or defendant, such litigation would be time-consuming, force us to incur significant costs and divert our attention and the efforts of our management and other employees, which could, in turn, result in lower revenue and higher expenses.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how.

We rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally seek to protect this proprietary information by entering into confidentiality agreements, or consulting, services or employment agreements that contain non-disclosure and non-use provisions with our employees, consultants, contractors, scientific advisors and third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information.

We have limited control over the protection of trade secrets used by our third-party manufacturers and suppliers and could lose future trade secret protection if any unauthorized disclosure of such information occurs. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, contractors, scientific advisors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain protection for our proprietary information could adversely affect our competitive business position. Furthermore, laws regarding trade secret rights in certain markets where we operate may afford little or no protection to our trade secrets.

We also rely on physical and electronic security measures to protect our proprietary information, but we cannot provide assurance that these security measures will not be breached or provide adequate protection for our property. There is a risk that third parties may obtain and improperly utilize our proprietary information to our competitive disadvantage. We may not be able to detect or prevent the unauthorized use of such information or take appropriate and timely steps to enforce our intellectual property rights.

If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify certain of our products and have registered these trademarks in certain key markets. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

We may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties.

The conduct of our business, our products or product candidates may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. For example, certain of our competitors own patents and patent applications in areas relating to critical aspects of our business and technology, including the separation and purification of proteins, and these competitors may in the future allege that we are infringing on their patent rights. We may also be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks, copyrights or trade secrets. Third parties could therefore bring claims against us or our strategic partners that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if such a claim were brought against us or our strategic partners, we or they could be forced to permanently or temporarily stop or delay manufacturing or sales of the product or product candidate that is the subject of the suit.

If we are found to be infringing, misappropriating or otherwise violating the patent or other intellectual property rights of a third party, or in order to avoid or settle claims, we or our strategic partners may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or our strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened claims, we or our strategic partners are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition, to the extent that we gain greater visibility and market exposure as a public company in the United States, we face a greater risk of being involved in such litigation. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, opposition, re-examination and similar proceedings before the U.S. Patent and Trademark Office and its foreign counterparts and other regulatory authorities, regarding intellectual property rights with respect to our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace or to conduct our business in accordance with our plans and budget, and patent

litigation and other proceedings may also absorb significant management time.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. While we take steps to prevent our employees from using the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims successfully, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

A breakdown in our information technology systems could result in a significant disruption to our business.

Our operations are highly dependent on our information technology systems. If we were to suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting all our areas of activity, including our manufacturing, research, accounting and billing processes and potentially cause disruptions to our manufacturing process for products currently in production. We may also suffer from partial loss of information and data due to such disruption.

The implementation of the 2010 healthcare reform law in the United States may adversely affect our business.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "healthcare reform law"), is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% became effective as of January 1, 2010, and the volume of rebated drugs was expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. In addition, the new law establishes an abbreviated licensure pathway for products that are drugs made by a living organism or derived from a living organism, commonly referred to as biosimilars, to become FDA-approved biological products, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars. Over the past few years, President Obama has submitted budget proposals seeking to reduce the exclusivity period for biosimilars from 12 years to seven years.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the healthcare reform law cannot be known until these provisions are fully implemented and the Centers for Medicare and Medicaid Services and other federal and state agencies complete their issuance of applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. We will continue to evaluate the healthcare reform law, as amended, the implementation of regulations or guidance related to various provisions of the healthcare reform law by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time.

In addition, Federal, state and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could have an adverse impact on our ability to market products and generate revenues in the United States and foreign countries.

Certain of our business practices could become subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug and Cosmetic Act (the "FDCA"), the Federal False Claims Act (the "FCA"), the Public Health Service (the "PHS Act") or a provision of the U.S. Social Security Act known as the "Anti-Kickback Law," or any regulations promulgated under their authority may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, the Department of Defense, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs and devices for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Significant enforcement activity has been the result of actions brought by relators, who file complaints in the name of the United States (and if applicable, particular states) under federal and state False Claims Act statutes and can be entitled to receive up to 30% of total recoveries. Also, violations of the False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to $11,000 per claim. The healthcare reform law imposes new reporting and disclosure requirements for pharmaceutical and medical device manufacturers with regard to a broad range of payments, ownership interests, and other transfers of value made to certain U.S. healthcare providers, such as physicians and teaching hospitals. Data collection obligations under this rule commenced on August 1, 2013, and the first disclosures under the law are due in 2014. On February 5, 2013, the Centers for Medicare and Medicaid Services ("CMS") issued final regulations to implement these provisions. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where practices have been found to involve improper incentives to use products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

To market and sell our products outside the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, and in such case, we would be precluded from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required

to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive and may not show an advantage in cost-efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the FCPA, the United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as HHS's Office of Inspector General ("OIG"), have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. We have not adopted U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations, but even if we do, having such a program can be no assurance that we will avoid any compliance issues.

We could be adversely affected if other government or private third-party payors decrease or otherwise limit the amount, price, scope or other eligibility requirements for reimbursement for the purchasers of our products.

Prices in many of our principal markets are subject to local regulation and certain pharmaceutical products, such as plasma-derived protein therapeutics, are subject to price controls. In the United States, where pricing levels for our products are substantially established by third-party payors, a reduction in the payors' amount of reimbursement for a product may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace or where changes in reimbursement rates induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products has affected, and may continue to materially adversely affect, our ability to maintain or increase gross margins.

Also, the intended use of a drug product by a physician can affect pricing. Physicians frequently prescribe legally available therapies for uses that are not described in the product's labeling and that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. These off-label uses are common across medical specialties, and physicians may believe such off-label uses constitute the preferred treatment or treatment of last resort for many patients in varied circumstances. If reimbursement for off-label uses of products is reduced or eliminated by Medicare or other third-party payors, including those in the United States or the European Union, we could be adversely affected. For example, the CMS could initiate an administrative procedure known as a National Coverage Determination ("NCD"), by which the agency determines which uses of a therapeutic product would be reimbursable under Medicare and which uses would not. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

We are subject to extensive environmental, health and safety, and other laws and regulations.

Our business involves the controlled use of hazardous materials, various biological compounds and chemicals. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or foreign laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms

and conditions of, required environmental or other permits or consents. In 2009 and 2010, we were subjected to audits by the Environmental Health Department of the Regional Health Bureau of the Israeli Ministry of Health ("IMOH") and the Ministry of Environmental Protection of Israel regarding wastewater and brine treatment at our production plant. As a result of these audits, the production plant undertook the necessary actions in order to comply with the regulations during 2013. However, we are still subject to future audits by those authorities and may be required to perform additional actions from time to time in order to comply with these guidelines and their requirements. We do not expect the costs of complying with these guidelines to be material to our business. See "Item 4. Information on the Company — Environmental."

Under the Israeli Restrictive Trade Practices Law, 5758-1988 (the "Restrictive Trade Practices Law"), a company that supplies or acquires more than 50% of any product or service in Israel is deemed to be a monopoly. The monopolist is prohibited from participating in certain business practices, including unreasonably refusing to sell products or provide services over which a monopoly exists, charging unfair prices for such products or services, and abusing its position in the market in a manner which might reduce business competition or harm the public. In addition, the General Director of the Israeli Antitrust Authority may determine that a company is a monopoly and has the right to order such company to change its conduct in matters that may adversely affect business competition or the public, including by imposing restrictions on its conduct. Depending on the analysis and the definition of the relevant product markets in which we operate, we may be deemed to be a "monopoly" under the Israeli Antitrust Law with respect to certain of our products.

We have recently signed a collective bargaining agreement with the employees' committee and the Histadrut (General Federation of Labor in Israel), and we could incur additional labor costs or experience work stoppages as a result of any disputes in connection with such agreement.

In February 2013, we were notified by the Histadrut (General Federation of Labor in Israel) that more than one-third of our employees at our Beit Kama facility had decided to join the Histadrut and that they have established an employees' committee. Following negotiation we signed, in December 2013, a collective bargaining agreement with the employees' committee and the Histadrut. In the process of negotiating such agreement, two work stoppages occurred. Although such work stoppages did not have a material adverse effect on our business or financial condition, any future disputes with the committee and the Histadrut over the implementation of the collective bargaining agreement may lead to additional labor costs and/or work stoppages, which could adversely affect our business operations, including through a loss of revenue and strained relationships with customers.

The requirements of being a public company in the United States, as well as in Israel, may strain our resources and distract our management, which could make it difficult to manage our business, particularly after we are no longer an "emerging growth company."

As a public company whose shares are being traded in the United States, as well as in Israel, we are required to comply with various regulatory and reporting requirements, including those required by the U.S. Securities and Exchange Commission (the "SEC"). Complying with these reporting and regulatory requirements is time consuming, and may result in increased costs to us and could have a negative effect on our business, results of operations and financial condition.

As a public company in the United States, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the requirements of S-OX. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual and current reports with respect to our business and financial condition. S-OX requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. To maintain and improve the effectiveness of our disclosure controls and procedures, we may need to commit significant resources, hire additional staff and provide additional management oversight. We will be implementing additional procedures and processes for the purpose of addressing the standards and requirements applicable to public companies in the United States. These activities may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations.

As an “emerging growth company,” as defined in the JOBS Act, we take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of S-OX (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them.

Our share price may be volatile.

The market price of our ordinary shares is highly volatile and could be subject to wide fluctuations in price as a result of various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our financial condition and operating results;
- overall conditions in the specialty pharmaceuticals market;
- loss of significant customers or changes to agreements with our strategic partners;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors’;
- announcements of clinical trial results, technological innovations, significant acquisitions, strategic alliances, joint ventures or capital commitments by us or our competitors;
- changes in key personnel;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the issuance of new or updated research reports by securities analysts;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- announcement of, or expectation of, additional financing efforts;
- sales of our ordinary shares by us or our shareholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- adverse events associated with our products;
- the expiration of contractual lock-up agreements with our executive officers and directors; and
- general political, economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market price of equity securities of many companies. Broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of our ordinary shares.

In the past, companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may also be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If equity research analysts issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares could decline if one or more securities analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Future sales of our ordinary shares in the public market could cause our share price to fall.

Sales by us or our shareholders of a substantial number of our ordinary shares in the public market, either on the Tel Aviv Stock Exchange (the "TASE") or Nasdaq, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2013, we have 35,959,939 ordinary shares outstanding, assuming no exercise of our outstanding options, warrants or conversion of our convertible debt as of December 31, 2013.

Except for shares held by our affiliates as contemplated by Rule 144 and the Securities Act of 1933, as amended (the "Securities Act"), all of the ordinary shares that are outstanding as of December 31, 2013, as well as the 4,101,932 ordinary shares issuable upon exercise of outstanding options, or our convertible debentures, will be freely tradable in the United States without restrictions or further registration under the Securities Act. Approximately 24.82% of our outstanding ordinary shares are beneficially owned by affiliates. These entities could resell the shares into the public markets in the United States in the future in accordance with the requirements of Rule 144, which include certain limitations on volume.

In addition, Damar Chemicals Inc., a company registered in Panama ("Damar"), Leon Recanati, Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("Gov") and wholly-owned by Mr. Recanati, and David Tsur and their respective affiliates are entitled to require that we register their 7,234,839 shares under the Securities Act for resale into the public markets in the United States. All shares sold pursuant to an offering covered by such registration statement will be freely tradable in the United States, except for shares purchased by affiliates.

The significant share ownership positions of the estate of Ralf Hahn, the former Chairman of our board of directors, and Leon Recanati, the Chairman of our board of directors, may limit our shareholders' ability to influence corporate matters.

The estate of Ralf Hahn, the former Chairman of our board of directors, and Leon Recanati, the Chairman of our board of directors, own, directly and indirectly, 13.36% and 9.52% of our outstanding ordinary shares, respectively, as of December 31, 2013. Accordingly, if the estate of Ralf Hahn and Leon Recanati vote the shares that they own or control together, they will be able to significantly influence the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. Their interests may not be consistent with those of our other shareholders. In addition, these parties' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares. On March 6, 2013, a shareholders agreement was entered into, effective March 4, 2013, pursuant to which Mr. Recanati and any company controlled by him (collectively, the "Recanati Group"), on the one hand, and Damar, TUTEUR S.A.C.I.F.I.A ("Tuteur") (companies formerly controlled by Mr. Ralf Hahn) and their affiliates (collectively, the "Damar Group"), on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. We are not party to such agreement or bound by its terms.

Our ordinary shares are traded on more than one market and this may result in price variations.

Our ordinary shares have been traded on the TASE since August 2005, and on Nasdaq since May 2013. Trading in our ordinary shares on these markets takes place in different currencies (U.S. dollars on Nasdaq and NIS on the TASE), and at different times (resulting from different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on the TASE could cause a decrease in the trading price of our ordinary shares on Nasdaq.

Our U.S. shareholders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders (as defined in "Item 10. Additional Information — E. Taxation — United States Federal Income Taxation"), and having interest charges apply to distributions by us and the proceeds of share sales. See "Item 10. Additional Information — E. Taxation — United States Federal Income Taxation."

We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies.

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We also have four months after the end of each fiscal year to file our annual reports with the SEC and are not required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders are exempt from the requirements to report short-swing profit recovery contained in Section 16 of the Exchange Act.

As we are a "foreign private issuer" and follow certain home country corporate governance practices, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements.

As a foreign private issuer, we have the option to follow certain Israeli corporate governance practices rather than those of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws, and provided that we disclose the requirements we are not following and describe the home country practices we follow instead. We have relied on this "foreign private issuer exemption" with respect to shareholder approval requirements in respect of equity issuances and equity-based compensation plans, the requirement to have independent oversight on our director nominations process and the quorum requirement for meetings of our shareholders. In addition, we rely on the "foreign private issuer exemption" with respect to the Nasdaq requirement to have a formal charter for the compensation committee. We may in the future elect to follow home country practices in Israel with regard to other matters. As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements. See "Item 16G. Corporate Governance."

We do not intend to pay dividends.

We have not recently declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. Any future agreements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We have not yet determined whether our existing internal controls over financial reporting are compliant with Section 404 of S-OX, and we cannot assure you that there are no material weaknesses or significant deficiencies in our existing internal controls.

Section 404(a) of S-OX and the related rules adopted by the SEC and the Public Company Accounting Oversight Board will require our management to report on the effectiveness of our internal control over financial reporting beginning with the second annual report that we file with the SEC after the completion of our initial public offering in the United States. Beginning with that same report, Section 404(b) of S-OX will require our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting, although as an "emerging growth company" under the JOBS Act, we have the option, which we have utilized, to defer compliance with the requirements of Section 404(b) until we no longer qualify as an "emerging growth company," as described below.

We have not yet begun the process of determining whether our existing internal controls over financial reporting are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. It could, therefore, divert internal resources and take a significant amount of time, effort and expense to complete.

In addition, we cannot predict whether we will determine that we have effective controls over financial reporting or whether we will need to implement remedial actions in order to implement effective controls. This determination and any required remedial actions could result in our incurring additional, unexpected costs. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. Further, any failure of our internal controls could result in an adverse opinion from

our auditors or have a material adverse effect on our stated results of operations, either of which could harm our reputation and cause investors to lose confidence in the reliability of our financial reporting, thereby adversely affecting the value of our ordinary shares.

We are an “emerging growth company” with reduced reporting requirements that may make our ordinary shares less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and have taken advantage of certain exemptions from various reporting requirements that are applicable to public companies generally. As discussed above, for so long as we remain an emerging growth company, we elected not to have our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting, as would otherwise be required by Section 404(b) of S-OX. This may increase the risk that we fail to detect and remedy any weaknesses or deficiencies in our internal control over financial reporting.

In general, these reduced reporting requirements allow us to refrain from disclosing information that you may find important. It is also possible that investors may generally find our ordinary shares less attractive because of our status as an emerging growth company and our more limited disclosure. Any of the foregoing could adversely affect the price and liquidity of our ordinary shares.

We anticipate taking advantage of these disclosure exemptions until we are no longer an “emerging growth company.” We will cease to be an “emerging growth company” upon the earliest of:

- December 31, 2018, which is the last day of the fiscal year in which the fifth anniversary of our initial public offering in the United States has occurred;
    - the last day of the fiscal year in which our annual gross revenues are $1 billion or more;
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or
- the last day of any fiscal year in which the market value of our ordinary shares held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

Risks Relating to Our Incorporation and Location in Israel

Conditions in Israel could adversely affect our business.

We are incorporated under Israeli law and our principal offices and manufacturing facilities are located in Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there has been an increase in unrest and terrorist activity, which began in September 2000 and has continued with varying levels of severity through 2013. Starting in December 2008, for approximately three weeks, Israel engaged in an armed conflict with Hamas in the Gaza Strip, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In November 2012, for approximately one week, Israel experienced a similar armed conflict, resulting in hundreds of rockets being fired from the Gaza Strip and disrupting most day-to-day civilian activity in southern Israel, the location of our manufacturing facility. In the event that our facilities are damaged as a result of hostile action or hostilities otherwise disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our ability to manufacture and deliver products to customers could be materially adversely affected.

Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel

or political instability in the region continues or increases. These restrictions may limit materially our ability to obtain raw materials from these countries or sell our products to companies in these countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturn in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our sales to decrease and adversely affect the share price of publicly traded companies having operations in Israel, such as us.

Our operations may be disrupted by the obligations of personnel to perform military service.

As of December 31, 2013, we had 289 employees, all of whom were based in Israel. Our employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to active duty. In response to increased tension and hostilities, there have been since September 2000 occasional call-ups of military reservists, including in connection with the mid-2006 war in Lebanon, and the December 2008 and November 2012 conflicts with Hamas, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations, in which event our ability to deliver products to customers may be materially adversely affected.

The tax benefits that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

One of our Israeli facilities has “Approved Enterprise” status granted by the Investment Center of the Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor) of the State of Israel (the “Investment Center”), under the Israeli Law for the Encouragement of Capital Investments, 1959 (the “Investment Law”), which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which will apply to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status will expire at the end of 2017.

Additionally, we have obtained a tax ruling from the Israeli Tax Authority according to which, among other things, our activity has been qualified as an “industrial activity,” as defined in the Investment Law, and is also eligible for tax benefits as a “Privileged Enterprise,” which will apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status are scheduled to expire at the end of 2021.

In order to remain eligible for the tax benefits of an Approved/Privileged Enterprise, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended. In addition, in order to remain eligible for the tax benefits available to the Approved Enterprise, we must also comply with the criteria set forth in the applicable certificate of approval, and in the case of the Privileged Enterprise, we must also comply with the conditions set forth in the tax ruling. These conditions include, among other things, that the production, directly or through subcontractors, of all our products should be performed within certain regions of Israel. If we do not meet these requirements, the tax benefits would be reduced or canceled and we could be required to refund any tax benefits that we received in the past, in whole or in part, linked to the Israeli consumer price index, together with interest. Further, these tax benefits may be reduced or discontinued in the future. For example, while we do not expect that the transfer of manufacturing of Glassia to Baxter would result in the reduction or loss of these tax benefits, the Israeli Tax Authority may determine otherwise. If these tax benefits are canceled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies was 25% in 2013 and has increased to 26.5% for 2014. For more information about applicable Israeli tax regulations, see “Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs.”

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In the future, we may not be eligible to receive additional tax benefits under the Investment Law if we increase certain of our activities outside of Israel. Additionally, in the event of a distribution of a dividend from the abovementioned tax exempt income, in addition to withholding tax at a rate of 15% (or a reduced rate under an applicable double tax treaty), we will be subject to tax on the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the corporate tax rate applicable to our Approved/Privileged Enterprise's income, which would have been applied had we not enjoyed the exemption. Similarly, in the event of our liquidation or a share buyback, we will be subject to tax on the grossed up amount distributed or paid at the corporate tax rate which would have been applied to our Privileged Enterprise's income had we not enjoyed the exemption. For more information about applicable Israeli tax regulations, see "Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs."

It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.

We are incorporated in Israel. None of our directors and executive officers are residents of the United States and the Israeli experts named in this Annual Report are located in Israel. The majority of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or Israeli court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Your rights and responsibilities as our shareholder are governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote, or to appoint or prevent the appointment of an office holder in the company has a duty to act in fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. See "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Duties of Shareholders." Since Israeli corporate law underwent extensive revisions approximately 15 years ago, the parameters and implications of the provisions that govern shareholder behavior have not been clearly determined. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

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Provisions of Israeli law and our articles of association may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Certain provisions of Israeli law and our articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a company are purchased. Under our articles of association, a merger shall require the approval of 66% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to certain mergers, Israeli tax law may impose certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger. See “Item 10. Additional Information — B. Memorandum and Articles of Association — Acquisitions Under Israeli Law.”

Item 4. Information on the Company

Corporate Information

We were founded in Israel in 1990. In August 2005, we successfully completed an initial public offering on the TASE. In June 2013, we successfully completed an initial public offering in the United States on Nasdaq. The address of our principal executive office is 7 Sapir St., Kiryat Weizmann Science Park, P.O. Box 4081, Ness Ziona 74140, Israel, and our telephone number is +972 8 9406472. Our website address is www.kamada.com. The reference to our website is intended to be an inactive textual reference and the information on, or accessible through, our website is not intended to be part of this Annual Report.

We have irrevocably appointed Puglisi & Associates as our agent to receive service of process in any action against us in any United States federal or state court. The address of Puglisi & Associates is 850 Library Avenue, Suite 204, P.O. Box 885, Newark, Delaware 19715.

Emerging Growth Company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”). Thus, we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies generally. For example, we have elected not to have our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting, as would otherwise be required by Section 404(b) of the Sarbanes-Oxley Act (“S-OX”).

We will cease to be an “emerging growth company” upon the earliest of:

- December 31, 2018, which is the last day of the fiscal year in which the fifth anniversary of our initial public offering in the United States has occurred;
    - the last day of the fiscal year in which our annual gross revenues are $1 billion or more;
-

the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or

- the last day of any fiscal year in which the market value of our ordinary shares held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

The JOBS Act also provides that an “emerging growth company” can utilize the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. However, we have chosen to “opt out” of such extended transition period, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for companies that are not “emerging growth companies.” Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

Capital Expenditures

For a discussion of our capital expenditures, see “Item 5. Operating and Financial Review and Prospects—Liquidity and Capital Resources.”

Business Overview

We are an orphan drug focused, plasma-derived protein therapeutics company with an existing marketed product portfolio and a robust late-stage product pipeline. We develop and produce specialty plasma-derived protein therapeutics and currently market these products through strategic partners in the United States and directly, through local distributors, in several emerging markets. We use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce AAT in a high purity, liquid form, as well as other plasma-derived proteins. AAT is a protein derived from human plasma with known and newly discovered therapeutic roles given its immuno-modulatory, anti-inflammatory, tissue protective and antimicrobial properties. Our flagship product, Glassia, is the first and only liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA. We market Glassia through a strategic partnership with Baxter International Inc. in the United States. Additionally, we have a product line consisting of ten other injectable pharmaceutical products which are marketed, in addition to Glassia, in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe and Asia. We currently have five plasma-derived protein products in our development pipeline, including Inhaled AAT for AATD, for which we completed a pivotal Phase II/III clinical trial in Europe and are expecting top line results by late April or early May of 2014 and have entered into Phase II clinical trials in the United States. In addition, we leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing eleven complementary products in Israel that are manufactured by third parties.

Glassia is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD. AAT is a naturally occurring protein found in a derivative of plasma known as fraction IV which regulates the activity of certain white blood cells known as neutrophils and reduces cell inflammation. Patients with genetic AATD suffer from a chronic inflammatory state, lung tissue damage and a decrease in lung function. We believe that our second generation AAT product, Inhaled AAT for AATD, is currently the only aerosolized AATD treatment in advanced stages of clinical development. We believe that Inhaled AAT for AATD will increase patient convenience and reduce the need for patients to use intravenous infusions of AAT products, thereby further reducing the risk of infection, decreasing the need for clinic visits or nurse home visits and reducing medical costs. In addition, because Inhaled AAT for AATD would be delivered directly to the affected tissue through a nebulizer using a lower dosage, we believe that this product, if approved, will enable us to treat significantly more patients from the same amount of plasma and production capacity and therefore increase our profitability. Additionally, we have successfully completed Phase II clinical studies in Israel for newly diagnosed Type-1 diabetes and have initiated a Phase II/III clinical study for this indication in Israel. We have also successfully completed Phase II clinical studies in Israel for additional novel indications for our AAT products, for cystic fibrosis and bronchiectasis, and we are advancing these new indications in further clinical development.

Our products are produced using our advanced proprietary technologies and know-how for the separation and purification of proteins derived from human plasma. We produce our plasma-derived protein therapeutics in our state-of-the-art, cGMP compliant, FDA-approved, large scale production facility located in Beit Kama, Israel.

We operate in two segments: the Proprietary Products segment, in which we develop and manufacture plasma-derived therapeutics and market them in more than 15 countries, and the Distribution segment, in which we distribute drugs manufactured by third-parties for critical use in Israel, most of which are produced from plasma or its derivative products. We have derived approximately 41%, 43% and 41% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively, from sales in the United States, approximately 9.5%, 5% and 1% of our total

revenues in the years ended December 31, 2013, 2012 and 2011, respectively, from sales in Europe, approximately 4%, 5% and 5% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively, in Asia (excluding Israel) and 8.4%, 6% and 5% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively, from Latin America.

Our Product Portfolio

Our products include plasma-derived protein therapeutics that are either produced in our Proprietary Products segment or marketed and sold in our Distribution segment.

Proprietary Products Segment

Our products in the Proprietary Products segment consist of plasma-derived protein therapeutics that are administered by injection or infusion. We also manufacture certain products from synthetic raw materials or from raw materials derived from animal sources.

We currently have products that target four product categories: respiratory, immunoglobulins, critical care and other. Our flagship product in the Proprietary Products segment is Glassia, sales of which, for the years ended December 31, 2013, 2012 and 2011, comprised approximately 54%, 73% and 40% of our total revenues, respectively, in the Proprietary Products segment. Revenue from our intravenous AATD products comprised approximately 49%, 47% and 44% of our total revenues for the years ended December 31, 2013, 2012 and 2011, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2013, 2012 and 2011 accounted for the substantial balance of total revenues in the Proprietary Products segment. The following table sets forth our primary products for each treatment category in our Proprietary Products segment.

Product	Indication	Active Ingredient	Geography
Respiratory			
Glassia (or Respira/RespiKam/Ventia in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (human)	United States, Israel, Russia*, Slovenia, Brazil, Croatia and Argentina*
Immunoglobulins			
KamRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (human)	Israel, India, Thailand, El Salvador, Singapore, Russia*, and Mexico* and Korea
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (human)	Israel, Brazil, India, Argentina, Chile*, El Salvador, Sri Lanka, Russia, Kenya, Nigeria, Sri Lanka* and the Palestinian Authority
KamRho (D) IV	Treatment of immune thermobocytopunic purpura	Rho(D) immunoglobulin (human)	Israel, India and Argentina*
Snake bite antiserum	Treatment of snake bites by the Vipera palaestinae and Echis coloratus	Anti snake venom	Israel
Other Products			
Heparin Lock Flush	To maintain patency of indwelling IV catheter	Heparin sodium	Israel

	designed for intermittent injection therapy or blood sampling		
Kamacaine 0.5%	Local or regional anesthesia or analgesia during surgery, diagnostic and therapeutic procedures and obstetrical procedures. Spinal anesthesia for surgery	Bupivacaine HCl	Israel
Human transferrin (diagnostical grade)	Not for human use	Transferrin	United States, Israel, Germany and Netherlands

* We have regulatory approval, but have not marketed the product in this country in 2013.

Respiratory — Glassia

Glassia is an intravenous AAT product produced from fraction IV that is indicated by the FDA for chronic augmentation and maintenance therapy in adults with emphysema due to congenital AATD. While Glassia does not cure AATD, it supplements the patient's insufficient physiological levels of AAT and is administered as a chronic treatment. As such, the patient must take Glassia indefinitely over the course of his or her life in order to maintain the benefits provided by it.

In the United States and Europe, we believe that AATD is currently significantly under-identified and under-treated, as we estimate that only approximately 5% and 2% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 200,000 patients suffering from AATD, of which less than 10% have been diagnosed. According to a 2011 report of the Marketing Research Bureau, the annual cost to the patient of AATD treatment is between $80,000 and $100,000 per patient. In the United States, in some of the European countries and in Israel, we believe that the majority of the cost of treatment is covered by medical insurance programs.

We estimate that the potential world market for AAT products is significantly larger than current consumption indicates. We believe that the primary reasons for this are the non-availability of AAT products in many countries, underdiagnosis of patients suffering from AATD, expensive and protracted registration processes required to commence sales of AAT products in new markets and the absence of insurance reimbursement in various countries. As AATD can be diagnosed with a simple blood test, we expect diagnosis of AATD to increase.

Glassia is the only AAT product in the world that is approved for use in a high purity liquid state which is ready for infusion and does not require reconstitution and mixing before injection, as is required from competing products. Glassia has a number of advantages over other intravenous AAT products, including the reduction of the risk of contamination during the preparation and infection during the infusion, reduced potential for allergic reactions due to the absence of stabilizing agents, simple and easy use by the patient or nurse, and the possible reduction of the nurse's time during home visits, in the clinic or in the hospital.

Currently, Glassia has been approved in five countries. It is sold in three of those countries and also is sold in two additional countries, where it has not been approved, on a compassionate use basis. The majority of sales of Glassia are in the United States, where Glassia was approved by the FDA in July 2010 and sales began in September 2010. As part of the approval, the FDA requested that we conduct Phase IV clinical trials, as is common in the pharmaceutical industry, aimed at collecting additional safety and efficacy data for Glassia. In 2010, we submitted our proposed Phase IV clinical trials to the FDA, which we have not yet begun. Pursuant to our agreement with Baxter described below, we expect that the Phase IV clinical trials will be financed by Baxter.

We market Glassia in the United States through our partnership with Baxter and by ourselves, and through our distributors in four countries. Sales to Baxter accounted for approximately 40%, 42% and 41% of our total revenues in the years ended December 31, 2013, 2012 and 2011, respectively. We plan to submit Glassia for marketing approval in additional countries. Revenues from our intravenous AATD products have grown from approximately $0.6 million in 2009 to $27.2 million in 2013, representing a 160% compound annual growth rate.

Immunoglobulins

KamRAB

KamRAB is a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is plasma that contains high levels of antibodies from donors that have been previously exposed to rabies. KamRAB is administered by a one-time injection, and the precise dosage is a function of the patient's weight.

According to the World Health Organization, about 10 million people throughout the world require medical treatment against rabies every year after being bitten by animals suspected of being infected. We believe that there are market opportunities for KamRAB in developing countries and in the United States. In many developing countries, patients do not receive treatment for suspected rabies due to the lack of availability of healthcare resources. In the United States, there is currently only one significant provider of anti-rabies immunoglobulin and we believe that healthcare providers may seek to diversify their source of supply if a competing high-quality product were approved for sale.

We began selling KamRAB in certain countries in Asia and Latin America in 2003, where sales of the product have steadily increased. We sell KamRAB in six countries, received regulatory approval to market KamRAB in three other countries and are pursuing market approval in the United States. In April 2007, we received approval from the FDA to commence Phase II/III clinical trials of KamRAB and in January 2010, the FDA approved significantly shorter clinical trials. The trial, which was designed as a prospective, randomized, double-blind, non-inferiority study, began in the second quarter of 2013. The trial evaluates the safety and effectiveness of KamRAB and assesses whether KamRAB interferes with the development of self-active antibodies. During February 2014, patient enrollment to the trial was completed. We hope to complete these trials by the second half of 2014 and if we obtain FDA approval, launch KamRAB in the United States in 2015. In July 2011, we signed a strategic agreement with Kedrion S.p.A for the clinical development and marketing in the United States of KamRAB, pursuant to which Kedrion agreed to bear all the costs required for the Phase II/III clinical trials. See "— Strategic Partnerships — Kedrion."

KamRho (D)

KamRho (D) is indicated for (i) the prevention of hemolytic disease of the newborn ("HDN"), which is a blood disease that occurs where the blood type of the mother is incompatible with the blood type of the fetus; and (ii) the treatment of immune thrombocytopenic purpura ("ITP"), which is thought to be an autoimmune blood disease in which the immune system destroys the blood's platelets, which are necessary for normal blood clotting. KamRho (D) is produced from hyper-immune plasma and is administered through intra-muscular injection (KamRho (D) IM) or through intravenous infusion (KamRho (D) IV).

According to academic research, approximately 15% of Caucasian women are Rh-negative and, if left untreated, HDN would affect one percent of all newborns and would be responsible for the death of one baby out of every 2,200 births. In addition, academic research estimates that ITP affects approximately five out of every 100,000 children per year, and two of every 100,000 adults per year worldwide, although some will recover without treatment. We have completed the registration process for Kam Rho (D), and are selling it in Israel and in another six countries in Latin America, Asia, Africa and Eastern Europe.

Snake Bite Antiserum

Our snake bite antiserum product is used for the treatment of humans that have been bitten by the most common Israeli viper (Vipera palaestinae) and by the Israeli Echis (Echis coloratus). The venom of these snakes is poisonous and causes, among other symptoms, severe immediate pain with rapid swelling. These snake bites can lead to death if

left untreated. Our snake bite antiserum is produced from hyper-immune serum that has been derived from horses that were immunized against Israeli viper and Israeli Echis venom. This product is the only treatment on the market for Israeli viper and Israeli Echis snake bites.

We developed the snake bite antiserum pursuant to an agreement with the IMOH entered into in March 2009. We completed construction of production facilities and laboratories for the product, and successfully passed the IMOH inspections. We began production in August 2011 and commenced sales to the IMOH in 2012. The agreement with the IMOH is renewable for up to ten additional one-year periods.

Other Products

We also sell additional critical care products including Heparin, an anticoagulant, and Kamacaine, an anesthetic for surgery or obstetric procedures and Transferrin, which is used as a cultural medium for diagnostic assays and cell cultures.

Distribution Segment

Our primary products in the Distribution segment include pharmaceuticals for critical use delivered by injection, infusion or inhalation. We leverage our expertise and presence in the plasma-derived protein therapeutics market to distribute products in Israel that we believe complement our products in the Proprietary Products segment. Most of the products in our Distribution segment are produced from plasma or plasma-derivatives, and are manufactured by European companies. We distribute these products in Israel on an exclusive basis. IVIG is our primary product in the Distribution segment, comprising approximately 64%, 73% and 47% of total revenues in the Distribution segment for the years ended December 31, 2013, 2012 and 2011, respectively. Sales of IVIG accounted for approximately 18%, 26% and 29% of our total revenues for the years ended December 31, 2013, 2012 and 2011, respectively.

The following table sets forth our primary products in our Distribution segment.

Product	Indication	Active Ingredient
Respiratory		
Bramitob	Management of chronic pulmonary infection due to pseudomonas aeruginosa in patients six years and older with cystic fibrosis	Tobramycin
Immunoglobulins		
IVIG 5%	Treatment of various immunodeficiency-related conditions	Gamma globulins (IgG) (human)
Varitect	Preventive treatment after exposure to the virus which causes chicken pox and zoster herpes	Varicella zoster immunoglobulin (human)
Hepatect CP	Prevent contraction of Hepatitis B by adults and children older than two years	Hepatitis B immunoglobulin (human)
Megalotect	Contains antibodies which neutralize cytomegalovirus viruses and prevent their spread in immunologically impaired patients	CMV immunoglobulin (human)
Critical Care		
Heparin sodium injection	Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis, pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	Heparin sodium
Albumin	Maintains a proper level in the patient’s blood plasma	Human serum Albumin
Coagulation Factors		
Factor VIII	Treatment of Hemophilia Type A diseases	

		Coagulation Factor VIII (human)
Factor IX	Treatment of Hemophilia Type B disease	Coagulation Factor IX (human)
Bupivacaine	Local or regional anesthesia or analgesia during surgery, diagnostic and therapeutic procedures and obstetrical procedures. Spinal anesthesia for surgery	Bupivacaine HCl

Our Product Pipeline and Development Program

We are in various stages of clinical development of new product candidates for our Proprietary Products segment. The following table sets forth our primary product pipeline in our Proprietary Products segment and each such product's stage of clinical trials:

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(1) "IV" represents intravenous administration of the product. "IH" represents inhaled administration of the product. "IM" represents intramuscular administration of the product.

(2) Phase I and II are complete in Israel. Phase II/III are completed in Europe (results expected by late April or early May 2014). Phase II began in first quarter of 2014 in the United States.

(3) Phase I and II are complete in Israel. Received approval of investigational new drug ("IND") application in the United States.

(4) Phase II/III trials in Israel for newly diagnosed cases of Type-1 diabetes began in first quarter of 2014.

(5) Phase II/III clinical trials - enrollment for the trial completed in first quarter of 2014.

(6) Orphan drug designation in the United States.

(7) Orphan drug designation in the European Union.

Inhaled Formulations of AAT

We are in various stages of development of inhaled formulations of AAT administered through the use of a custom-designed nebulizer co-developed with PARI for several indications in the respiratory field, including the treatment of AATD, cystic fibrosis and bronchiectasis.

AATD

We have been able to leverage our expertise gained from the production of Glassia to develop a stable, high purity Inhaled AAT for AATD, an inhaled AAT product candidate for the treatment of AATD. Existing treatments for AATD require weekly intravenous infusions of AAT therapeutics. We believe that Inhaled AAT for AATD will significantly improve the patient's disease condition and the quality of life of the patients versus current invasive weekly treatment that requires uncomfortable infusion, consumption of time and administration by a medical professional. If approved, Inhaled AAT for AATD will be the first AAT product that is not required to be delivered intravenously but, instead is administered by a user-friendly, lightweight and silent nebulizer in two short daily sessions. We believe that Inhaled AAT for AATD will increase patient convenience and reduce or replace the need for patients to use intravenous infusions of AAT products, thereby further reducing the risk of infection, decreasing the need for clinic visits or nurse home visits and reducing medical costs. Because of the smaller amount of AAT product used in Inhaled AAT for AATD (since it is applied directly to the site of action rather than administered systematically) we believe that this product, if approved, will enable us to treat significantly more patients from the same amount of plasma and production capacity and therefore increase our profitability.

The current standard care for AATD in the United States and in certain European countries is intravenous infusion of an AAT therapeutic. We estimate that only 2% of the AAT dose reaches the lung when administered intravenously. We have conducted a study demonstrating that administration of inhaled formulations of AAT through inhalation results in greater dispersion of AAT to the target lung tissue including the lower lobes and lung periphery. Accordingly, we believe that an inhaled formulation of AAT would require a significantly lower therapeutic dose and would be more effective in reducing inflammation of the lung tissue and inhibiting the uncontrolled neutrophil elastase that causes the breakdown of the lung tissue and emphysema. In addition, treatment by inhalation will enable the treatment of up to four to five times more patients with the same amount of AAT currently used by one patient for intravenous infusion. In addition, self-administration by inhalation is more convenient than intravenous infusion and would also reduce the burden on healthcare providers to administer treatments.

We are currently undergoing and preparing for clinical trials for Inhaled AAT for AATD, which has been designated as an orphan drug for the treatment of AATD in the United States and Europe. A Phase II/III pivotal trial under EMA guidance was completed in seven countries in Europe and in Canada. The trial, which was designed as a double blind placebo controlled and randomized trial, started in January 2010 and has been completed, and we expect top line results by late April or early May of 2014. A total of 168 patients were in the trial, with the last patient randomly selected in December 2012. Subjects in this trial were administered with a daily dose of Inhaled AAT for AATD or equivalent dose of placebo for 50 consecutive weeks. The primary endpoints for the trial were exacerbation events for which a sufficient number of events were already accumulated for the purpose of statistical analysis of the primary endpoint. Other endpoints, which were secondary and tertiary, included lung function, CT scan and quality of life. The trial was 80% powered based on the number of exacerbation events collected in the study, in order to detect a difference between the two groups one year later. A 20% difference between the two groups is required to prove efficacy and is considered to be clinically meaningful and would allow the decision to prescribe treatment. An open label extension of an additional 50 weeks on active drug was offered to study participants in most sites once they completed the initial 50 week period. As of today, approximately 70 patients have already been treated in the open label extension. Additionally, we completed a fifth blinded interim safety analysis in this trial. The interim safety analysis reports of these trials did not raise any safety concerns.

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During March 2014, we initiated Phase II trials in the United States. This trial may serve as a supplementary trial to the European Phase II/III trial and was designed to incorporate parameters required by the FDA. This is a Phase II, double-blind, placebo-controlled study to explore the ELF and plasma concentration as well as safety of Inhaled AAT in AATD subjects. The subjects will receive one of two doses of Inhaled AAT or placebo. Following the 12 week double blind period, the subjects will be offered to participate in an additional 12 weeks open label period during which they will receive only Inhaled AAT therapy. We completed the European trial in 2013 and intend to complete the United States trials in 2014 and file a marketing authorization application afterwards in 2014 in Europe. If we receive marketing authorization, we hope to launch Inhaled AAT for AATD in 2015 in Europe and 2016 in the United States.

An inhaled formulation of AAT was investigated in two separate Phase I trials (Phase Ia and Phase Ib). These trials were performed in accordance with the scientific advice provided by the EMA under the product's orphan designation status. In both trials, the inhaled formulation of AAT and the control product, a placebo, were administered using the "eFlow" nebulizer. Phase Ia was a single-blind, randomized, single-dose escalation, placebo-controlled study in 24 subjects. Phase Ib was a single-blind, randomized, repeated-dose, dose ranging, placebo-controlled study in 15 subjects. Both trials were targeted to explore safety and tolerability and were completed successfully, concluding high safety and tolerability of the product and no signs of immunogenicity or allergic reactions, allowing the continuation of the later development stages.

We conducted a Phase II lung deposition trial in three different subject populations: patients with cystic fibrosis, patients with emphysema and healthy subjects. The results of the Phase II trial indicated highly efficient deposition of AAT, including to periphery regions, lower lobes and mid and upper lobes. No safety issues were noted.

Cystic Fibrosis

We are currently developing an inhaled formulation of AAT for the treatment of cystic fibrosis, which has been designated as an orphan drug in Europe and the United States. Cystic fibrosis is a congenital disease that causes mucus to build up in the lungs, digestive tract and other areas of the body. The Cystic Fibrosis Foundation estimates that approximately 70,000 people suffer from cystic fibrosis throughout the world. The rate of diagnosis of new patients in the United States is approximately 1,000 per year. Treatment of cystic fibrosis continues throughout the patient's life, and standard treatments are currently limited to inhaled antibiotics and, in severe cases, lung transplantation.

During the second half of 2012, we received FDA approval for IND Phase II trials for the inhaled formulation of AAT for the treatment of AATD and cystic fibrosis, which we are currently in the process of developing. We are planning to start this trial during the second half of 2014.

Previously, in August 2008, we completed a Phase II trial in 21 cystic fibrosis patients. The trial was a double-blind, randomized, placebo-controlled, Phase II trial that sought to explore the safety and efficacy of an inhaled formulation of AAT in cystic fibrosis patients, and consisted of treatment periods of 1 day, 7 days and 28 days. No serious adverse events were reported in any of the patients and the safety listings did not indicate any safety concerns. The trial concluded that the product was safe and well tolerated when inhaled daily for 28 days. A reduction of neutrophils and neutrophil elastase in sputum was observed in the group receiving the inhaled formulation of AAT while no such reduction was observed in the placebo group. The results, while not statistically significant due to small sample size, suggested an anti-inflammatory effect through the usage of the inhaled formulation of AAT in cystic fibrosis patients.

Bronchiectasis

We are also in the process of developing an inhaled formulation of AAT for the treatment of bronchiectasis, which has been designated as an orphan drug in the United States. Bronchiectasis is an illness causing blockage and infection of

the lungs. According to research conducted by the Cystic Fibrosis Foundation, in the United States alone, there are 100,000 persons suffering from bronchiectasis. Throughout the world, it is estimated that there are about 600,000 persons suffering from bronchiectasis. Treatment of bronchiectasis continues throughout the patient's life.

While we have not yet sought approval for clinical trials in the United States, we presented the findings to the FDA of a Phase II trial we conducted in Israel, which was a double-blind, randomized, placebo-controlled trial in 21 bronchiectasis patients and aimed to explore the safety and efficacy of an inhaled formulation of AAT in bronchiectasis patients for 12 weeks. The safety profile demonstrated was high and the product was determined as safe and tolerable for a period of 12 weeks in bronchiectasis patients. Efficacy results were not statistically significant due to the small number of patients in the study and to variability of the patients' disease severity, but suggested a positive effect of AAT on decreasing inflammation of the lungs.

AAT by Infusion for Treatment of Newly Diagnosed Type-1 Diabetes

We have commenced the development of an additional indication for Glassia for its usage in the treatment of newly diagnosed cases of Type-1 Diabetes. Diabetes is an autoimmune disease in which the pancreatic beta cells responsible for secretion of insulin are attacked and destroyed by the immune system. According to estimates by the U.S. Centers for Disease Control, more than 10 million persons throughout the world suffer from Type-1 Diabetes with 100,000 new patients diagnosed annually. According to estimates by the American Association for Type-1 Diabetes, approximately three million people in the United States suffer from Type-1 Diabetes, with 30,000 new patients diagnosed annually.

Studies have demonstrated that even though the level of AAT protein in Type-1 Diabetes patients may be normal, the activity of the AAT protein in these patients is significantly lower than in healthy people. Because AAT has proven anti-inflammatory responses, we believe that treatment by AAT protein in the initial stages after diagnosis of Type-1 Diabetes may prevent or may delay the inflammation that is caused by the autoimmune destruction of the pancreatic cells. As a result, we believe that AAT therapeutics may slow the progression of the development of newly diagnosed Type-1 Diabetes and improve prognosis. A number of studies conducted recently, including those conducted using Glassia, as discussed below, have suggested that use of AAT protein may delay the inflammatory process in the pancreatic cells and maintain or prolong cell function, which is increased by the secretion of insulin and glycemic control. We believe that the use of Glassia for the treatment of newly diagnosed Type-1 Diabetes, unlike the current standard of care insulin treatment, may prevent or slow the progression of the development of the disease. If demonstrated in further clinical studies, we believe that this product can slow progression and delay the complications of diabetes, such as retinopathy, nephropathy and heart disease.

In December 2012, we completed Phase I/II clinical trials in Israel of human AAT (Glassia) for usage in the treatment of Type-1 Diabetes, which suggested that AAT may slow disease progression, allow continued functionality of beta cells and improve glycemic control. The objective of the trials was to examine the safety and efficacy of Glassia for treatment of newly diagnosed Type-1 Diabetes. The participants in the trials included 24 patients suffering from Type-1 Diabetes, between ages 9 and 17, who have been diagnosed as suffering from Type-1 Diabetes within the most recent six months. The extension portion of the trials showed positive preliminary data according to which, approximately 20 months from diagnosis and approximately 10 months following the last Glassia infusion, 60% of study subjects who participated in the extension portion of the trial had peak C-peptide levels greater than 0.2 pmol/ml, which indicates a functioning beta cell capacity and is considered to be a higher percentage than would be expected without intervention. In March 2014, we began double-blind, randomized, placebo-controlled, multicenter Phase II/III trials evaluating the efficacy and safety of Glassia in the treatment of new onset Type-1 Diabetes. Initially, these studies will be conducted at four pediatric Type-1 Diabetes medical centers in Israel. These studies will enroll 192 patients that will be randomized into tw